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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,546	04/23/2001	William M. Hammesfahr	003BUS	6691

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RICHARD COALE WILLSON JR
3205 HARVEST MOON DR
STE 200
PALM HARBOR, FL 34683-2127

EXAMINER	
JAWORSKI, FRANCIS J	

ART UNIT	PAPER NUMBER
3737	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,546	HAMMESFAHR	
	Examiner	Art Unit	
	Jaworski Francis J.	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *42104*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The finality of the previous action has been withdrawn due to the discovery of more relevant art.

Claims 32 – 44 remain present for examination in this case; claims 1 – 31 have been cancelled.

Parenthesized claim numbers following the rejected claims pertain to the specific claim or claims towards which the preceding rejection is directed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32 – 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al (US4650484, newly of record) in view of Stanley et al (US4885173, previously of record), further in view of Fung et al (US5278192, newly of record).

Shaw et al is directed to a transdermal delivery system which provides a daily 24 hour vasodilator dosage (col. 4 lines 7 – 11) at a rate of about 10 – 400 micrograms of vasodilator per hour (col. 4 lines 50 – 52) which is equivalent to 240 – 9600 micrograms per day or .24 – 9.6 milligrams per day total dosage.

Shaw et al defines such vasodilators to include a wide variety of organic nitrates and nitrites (col. 2 lines 35 – 50). Shaw et al do not discuss adaptability for vasospasm treatment or suggest the practice of dosage tapering. It would have been obvious however in view of Stanley et al to adapt the vasodilator delivery system of Shaw et al to use the organic nitrates to treat vasospasm since col. 3 lines 1 – 20 of Stanley et al which effectively merely serves as a pharmacologic teaching notes that this class of vasodilators like the calcium channel blockers have use in treating vasospasm and this pathology may be a varying component of angina towards the treatment of which such a drug would be transdermally directed, irrespective of the fact that Stanley et al in and of itself shows preference for a sustained oral (lollipop) delivery vehicle versus transdermal use. It would have been further obvious in view of Fung et al which although directed to treatment of congestive heart failure nonetheless teaches that when vasodilators such as organic nitrates or nitrites are used for continuous 24 hour transdermal patch therapy in amounts including those suggested by Shaw et al (in Fung et al amounts of 1 – 100mg/day are used, see col. 12 lines 13-18), side effects as well as tolerance quickly develope when dosages exceeding the minimum effective dose are provided and so specific suggestion is made regarding tapering usages towards titration of dose both upwards and downwards in dosage levels in order to set the final dosage, see page 6 lines 20-47 and page 12 lines 50-58. It would have been inherently obvious to include instructions to a physician or patient for using such potent pharmacologic agents which identify the dosage and taper issues in relation to the specific vascular

problem which is being treated, whether the malady is labeled via DRG grouping or other nomenclature.(Claims 32 – 35, 37.).

Cardiovascular illnesses such as anginal vasospasticity/vasoocclusion particularly when combined with heart failure are commonly considered to be systemic disorders (Claim 36).

Claims 38 – 44 are rejected under 35 USC 103 as obvious based upon Shaw et al in view of Stanley et al and Fung et al, further in view of Ragauskas et al (US5388583). The former are applied as discussed in relation to the preceding claims. These references taken together teach that a titrated organic nitrite or nitrate drug regimen e.g. nitroglycerin transdermal patch application in a very low milligram range of daily dosage delivery will treat vasospastic disorders however side-effects such as hypotension mimicking cerebral ischemia may occur, see Jung et al col. 6 lines 38 – 41. It would have been obvious therefore in view of Ragauskas et al col. 3 lines 24 – 39 to evaluate cerebral ischemia including for vasospaflow measuring probe such that one would be able to diagnose cerebral ischemia due to the vasodilators in use versus cerebral disease due to local vasospasm or due to a common arteriosclerotic process. Note further that all claims of this set do not exclude that the vasodilator may in fact be primarily treating vasospasm elsewhere than in within the cranium, hence the breadth of claiming tends to strengthen the rejection argument.

Response to Amendment Arguments

Responsive to arguments previously presented, the newly discovered art is being applied since unlike the prior rejection arguments against the claims based upon the Panoz patent, the specific daily titration dosage milligram range is explicitly stated in Shaw et al and Fung et al as well as a more direct argument for tapering of dosage in the latter. Additionally, insofar as Ragauskas et al specifically notes the applicability of transcranial Doppler for diagnoses involving cerebral ischemia including suspected or actual cerebral vasospasm, it effectively provides a more relevant argument than the transcranial Doppler system of the VanVeen patent previously applied.

This action is not made final however the case should be prepared for final action.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

12282004.

Francis J. Jaworski
Primary Examiner